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REMARKS

Reconsideration of the above application is respectfully requested.

There are four claims pending in this application. These are claims 12, 17 – 18 and 20. Original claims 1 – 11, 13 – 16 and 19 have been withdrawn from consideration as relating to non-elected subject matter. In this paper, Applicants have amended claim 17.

In the Office Action, the Examiner rejected claim 17 under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner stated that it is not clear from the language in claim 17 that reads, "wherein the alpha2delta ligand is a compound of the formula II[structure omitted] ... and the pharmaceutically acceptable salts thereof" whether Applicants intend the alpha2delta ligand to be a compound of formula II **and** its pharmaceutically acceptable salts, or a compound of the formula II **or** a pharmaceutically acceptable salt thereof. Applicants, by this Amendment, have amended claim 17 so that the phrase referred to above now reads, "wherein the alpha2delta ligand is a compound of the formula II [structure omitted] ... or a pharmaceutically acceptable salt thereof". Applicants respectfully traverse this rejection and submit that claim 17, as amended, is clear and precise with respect to the meaning of the alpha2delta ligand referred to therein, and that claim 17, as amended, is fully compliant with 35 U.S.C. § 112, second paragraph.

Applicants further submit, for the reasons that follow, that the amendment to claim 17 referred to above does not add new matter to the present application. On page 8 of the present specification, the following paragraph sets forth the following invention.

"This invention also relates to a method of treating a disorder or condition selected from the group consisting of movement disorders such as primary movement disorders, akinesias, dyskinesias (e.g., familial paroxysmal dyskinesia, tardive dyskinesia, tremor, chorea, myoclonus, tics and other dyskinesias) spasticities, Tourette's syndrome, Scott syndrome, palsys (e.g., Bell's palsy, cerebral palsy, birth palsy, brachial palsy, wasting palsy, ischemic palsy, progressive bulbar palsy and other palsys), akinetic-rigid syndrome; extra-pyramidal movement disorders such as medication-induced movement disorders, for example, neuroleptic-induced Parkinsonism, neuroleptic malignant syndrome, neuroleptic-induced acute dystonia, neuroleptic-induced acute akathisia, neuroleptic-induced tardive dyskinesia and medication-induced postural tremour; **restless legs syndrome** and movement disorders associated with Parkinson's disease or Huntington's disease in a mammal, comprising administering to a mammal in need of such treatment a therapeutically effective amount of an alpha2delta ligand or a pharmaceutically acceptable salt thereof." (emphasis added)

The above paragraph provides support for the invention of a method of treating restless legs syndrome comprising administering to a mammal in need of such treatment a therapeutically

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effective amount of an alpha2delta ligand or a pharmaceutically acceptable salt thereof. The following statement appears on page 9 of the present specification.

"The foregoing methods are also referred to herein, collectively, as the "invention methods".

The foregoing statement indicates that the method described in the larger quote above is one of the "invention methods".

The following statement appears on page 10 of the present specification.

"In other preferred embodiments, the invention methods utilize an alpha2delta ligand of Formula II ...[structure omitted] or a pharmaceutically acceptable salt thereof", ..."

The above quoted statements from the present specification, taken together, clearly disclose, as a preferred embodiment of the present invention, a method of treating restless legs syndrome comprising administering to a mammal in need of such treatment a therapeutically effective amount of ***an alpha2delta ligand that is a compound of the formula II or a pharmaceutically acceptable salt thereof.***

In view of the above, Applicants respectfully request that the rejection under 35 U.S.C. § 102 be withdrawn.

The Examiner also rejected claims 12, 17 – 18 and 20 under 35 U.S.C. § 102, as being anticipated by Brummel *et al.* (WO 01/01983;2001), hereinafter referred to as "Brummel". Applicants respectfully traverse this rejection, for the reasons that follow, and request that it be withdrawn. Brummel refers only to the use of a combination of pregabalin and gabapentin to treat several different types of pain, including pain associated with restless leg syndrome. Restless legs disorder ("RLS") has been classified as a neurological sensorimotor disorder, a movement disorder and a sleep disorder. People with RLS feel uncomfortable sensations in their legs, especially when sitting or lying down, accompanied by an irresistible urge to move about. While this disorder involves unpleasant sensations in the legs of a patient that create an urge to move the patient's legs, it is not considered a pain syndrome or disorder.

Treatment of the unpleasant sensations or "pain" associated with restless legs syndrome can not anticipate or even render obvious the treatment of restless legs syndrome because efficacy for the treatment of restless legs syndrome involves more than producing an analgesic effect. Efficacy in treating restless legs syndrome is measured by the patient rated international RLS scale, which is the International Restless Legs Syndrome (IRLS) Rating Scale, and the Clinical Global Impression of Improvement (CGI-I) Scale. Of the 10 items or questions in the IRLS, five pertain to the frequency and intensity of symptoms and five

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address the impact of the symptoms on aspects of daily living and sleep. None of the questions refer to pain. Item 1 asks "How would you rate the RLS *discomfort* in your legs or arms?" (emphasis added). Item 3 asks "How much relief from your RLS *discomfort* do you get from moving around?" (emphasis added). The CGI-I provides the investigator's global impression of a patient's improvement. GSK's *Requip*®, which was approved in May, 2005 for the treatment of moderate-to-severe primary RLS, became the first and only FDA-approved treatment for RLS of any type or severity. The data submitted to the FDA in support of GSK's application for approval of *Requip*® for the treatment of RLS included data from both these scales.

In view of the above, Applicant's submit that all pending claims of the present application, as amended, are patentable and they respectfully request that they be allowed to issue.

The Commissioner is authorized to charge any fee or credit any over payment in connection with this communication to our Deposit Account No. 23-0455.

Respectfully submitted,

Date:

9/6/06

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